

DRAFT REGULATORY GUIDE

C-228 (E)

DEVELOPING AND USING ACTION LEVELS

Issued for public comments by the
Atomic Energy Control Board
November 1999



Atomic Energy
Control Board

Commission de contrôle
de l'énergie atomique

Canada

AECB Regulatory Documents

The Atomic Energy Control Board (AECB) operates within a legal framework that includes law and supporting regulatory documents. Law includes such legally enforceable instruments as acts, regulations, licences and directives. Regulatory documents such as policies, standards, guides, notices, procedures and information documents support and provide further information on these legally enforceable instruments. Together, law and regulatory documents form the framework for the regulatory activities of the AECB.

The main classes of regulatory documents developed by the AECB are:

- **Regulatory Policy:** a document that describes the philosophy, principles and fundamental factors used by the AECB in its regulatory program.
- **Regulatory Standard:** a document that is suitable for use in compliance assessment and describes rules, characteristics or practices which the AECB accepts as meeting the regulatory requirements.
- **Regulatory Guide:** a document that provides guidance or describes characteristics or practices that the AECB recommends for meeting regulatory requirements or improving administrative effectiveness.
- **Regulatory Notice:** a document that provides case-specific guidance or information to alert licensees and others about significant health, safety or compliance issues that should be acted upon in a timely manner.
- **Regulatory Procedure:** a document that describes work processes that the AECB follows to administer the regulatory requirements for which it is responsible.

Document types such as regulatory policies, standards, guides, notices and procedures do not create legally enforceable requirements. They support regulatory requirements found in regulations, licences and other legally enforceable instruments. However, where appropriate, a regulatory document may be made into a legally enforceable requirement by incorporation in an AECB regulation, a licence or other legally enforceable instrument made pursuant to the *Atomic Energy Control Act*.

DRAFT REGULATORY GUIDE

Developing and Using Action Levels
C-2 (E)

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NOTICE

On March 20, 1997, Bill C-23, the *Nuclear Safety and Control Act* (NSC Act, the Act), received Royal Assent. New regulations that are derived from this Act will become law and replace the existing regulations. Draft Regulatory Guide C-228 references the *NSC Act* and new regulations, which will come into force in 2000 on a date to be fixed by order of the Governor in Council.

About this Document

Comments

In order for interested persons to determine this document's impact and value, public comments are being solicited. At the end of the period, all comments will be studied to determine how best to improve the document. Unless otherwise requested, a copy of all comments received will be placed in the AECB Library, in Ottawa. Comments on this guide will be most helpful if received in writing by December 31, 1999. Reference our file number 1-8-8-228, and direct enquiries and/or comments to the address below.

Document availability

The document can be viewed on the AECB internet website at www.aecb-ccea.gc.ca. A copy of C-228 may be ordered in English or French using the contact information below:

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Purpose

This Regulatory Guide is intended to help applicants for Canadian Nuclear Safety Commission (CNSC) licences to develop action levels in accordance with paragraph 3(1)(f) of the *General Nuclear Safety and Control Regulations* and section 6 of the *Radiation Protection Regulations*.

Scope

This guide applies to all applicants for a CNSC licence. It describes how they can develop action levels that provide for the radiation protection of workers and the public during CNSC-licensed activities.

1. Background

1.1 Regulatory framework and relevant legislation

The Atomic Energy Control Board (AECB) is the federal regulatory agency that regulates nuclear facilities and materials to prevent undue risk to health, safety, national security and the environment.

At present, the AECB operates under the authority of the *Atomic Energy Control (AEC) Act* and regulations. However, these laws are soon to be replaced by new legislation, the *Nuclear Safety and Control (NSC) Act* and associated regulations.

Under the *NSC Act*, the AECB will become the Canadian Nuclear Safety Commission (CNSC), with continuing responsibilities for regulation of the nuclear industry.

The *NSC Act* and regulations will prohibit persons or organizations from possessing, using, disposing or abandoning certain nuclear materials without a licence from the CNSC, unless they are exempted from such requirements. The regulations will also stipulate prerequisites for licensing, including the information that is to be or may be included in licence applications.

Paragraph 3(1)(f) of the proposed *General Nuclear Safety and Control Regulations* requires that an application for a CNSC licence contain certain information, including "any action level that the applicant considers appropriate for the purpose of section 6 of the *Radiation Protection Regulations*." In addition to defining what an action level is, section 6 of the proposed *Radiation Protection Regulations* stipulates:

"When a licensee becomes aware that an action level referred to in the licence for the purpose of this subsection has been reached, the licensee shall:

- (a) conduct an investigation to establish the cause for reaching the action level;*
- (b) identify and take action to restore the effectiveness of the radiation protection program implemented in accordance with section 4; and*
- (c) notify the Commission within the period specified in the licence."*

Under the proposed *Uranium Mines and Mills Regulations*, a combination of any action level, specified responses and associated notification procedures comprises a "code of practice."

1.2 Definition of an action level

Subsection 6(1) of the proposed *Radiation Protection Regulations* defines an action level as:

“a specific dose of radiation or other parameter that, if reached, may indicate a loss of control of part of a licensee's radiation protection program, and triggers a requirement for specific action to be taken.”

1.3 The licensing process and action levels

The CNSC licensing process begins when a person or organization applies for a licence.

Upon receipt of an application that is complete and in the prescribed form, the CNSC will review it to determine whether the applicant is competent and has made adequate provision for the protection of the environment, the health and safety of persons, and the maintenance of national security and measures required to implement international obligations to which Canada has agreed. If satisfied, the CNSC may issue a licence that contains relevant conditions. Typically, this licence will incorporate the applicant's commitments and will contain other conditions that the CNSC considers necessary.

Under subsection 24(5) of the *NSC Act*, the CNSC will be empowered to include in a licence any condition that it considers necessary for the purpose of the Act, including a condition that incorporates an action level. Upon receiving a CNSC licence, a licence applicant will become the licensee and will be obliged to comply with the conditions of the licence in performing the authorized activities.

As noted above, if an action level that is incorporated in a CNSC licence is reached, the *Radiation Protection Regulations* will further require that the licensee conduct an investigation, take appropriate action, and notify the CNSC within the time period specified in the licence.

2. Understanding and Using Action Levels

Many CNSC licensees may find action levels useful for gauging, controlling, assuring and demonstrating the effectiveness of the radiation protection programs that will be required under section 4 of the *Radiation Protection Regulations*. That is, under the *NSC Act* and regulations most licensees will be able to derive, implement and administer action levels so as to provide timely warning of the possible failure of any part of their radiation protection programs. In concert with any responses required pursuant to subsection 6(2) of the

Radiation Protection Regulations, action levels should help CNSC licensees ensure the radiation safety of workers and the public during authorized activities.

Some CNSC licensed activities, such as the use of fixed gauges, static eliminators or gas chromatographs, may not warrant action levels to assure radiation protection.

An action level will typically be established as part of the CNSC licensing process, in advance of the conduct of licensed activities. If it is to be useful and credible, a proposed action level must be a meaningful indicator over a defined time period of the state of the associated radiation protection program. Accordingly, the action level must be measurable to accepted standards of accuracy. To aid regulatory review, applicants for CNSC licences should substantiate any proposed action level by describing the basis of its derivation, and how it will be used within the context of a proposed radiation protection program.

When an action level is reached or exceeded, the occurrence should serve to alert those responsible to a possible change in operating conditions or a possible loss of control of a part of the radiation protection program, and should signal that follow up investigations or responses may be required.

An action level may be expressed in terms of any operational parameter that, if reached, may indicate a loss of control on the part of the licensee's radiation protection program. Accordingly, such parameters include:

- the quantity of radiation an individual receives ("individual dose"),
- the radiation level within a work area ("ambient dose rate"),
- radioactivity per unit surface area ("surface contamination level"),
- air-exchange rates in a work place ("ventilation rate"),
- the rate at which radioactive effluents are released to the environment ("emission rate," "discharge rate"), and
- a concentration or quantity of radioactive substance in the workplace or in effluent ("concentration", "loading").

Action levels are not regulatory limits, and, accordingly, exceeding an action level is not necessarily a violation of the *NSC Act* and regulations. However, if an action level that is specified in a licence is reached or exceeded, failure to notify, investigate or take appropriate action in response constitutes a contravention of applicable regulations, and as such will be an offence under the *NSC Act*.

3. Establishing Action Levels

Under section 3 of the proposed *General Nuclear Safety and Control Regulations*, applicants for CNSC licences will be required to propose any action level that the applicants consider appropriate to detect a loss of control of part of their respective radiation protection programs.

Where possible, action levels should be based on facility design and the operating experience of the proponent. However, a proponent who lacks such experience, as in the case of new activities or operations, may be able to draw upon the experience of comparable designs and operations. To facilitate regulatory review of any proposed action level, the licence applicant should thoroughly and clearly explain its basis of derivation and proposed application.

Accordingly, the following steps to deriving and implementing action levels may be useful to applicants for CNSC licensees:

- From the design, identify those processes and activities that could result in doses to workers or the public.
- For activities and processes that could result in doses to workers or the public, identify the measurable parameters that will be indicative, directly or indirectly, of whether the corresponding radiation protection program is adequately controlled.
- On the basis of realistic assumptions, select appropriate action levels, expressed in terms of the appropriate parameters, for all key processes and activities.
- Incorporate use of the proposed action levels into the proposed radiation protection program.
- Implement the radiation protection program and the associated action levels in accordance with the corresponding CNSC licence.
- As operating experience accumulates, refine action levels accordingly.

4. Monitoring

To detect when any action level is reached or exceeded, licensees must implement effective monitoring activities. Typically, monitoring proposals, including those associated with proposed action levels, are required and submitted as part of licence applications. These proposals should include a proposed methodology and frequency of sampling or measurement. When a monitoring proposal is accepted and incorporated into a CNSC licence, the licensee must ensure that the associated program is implemented and maintained in accordance with the licence.

5. Responding when an Action Level is Reached

By definition, if an action level is reached, a loss of control of part of a licensee's radiation protection program may have occurred, and certain follow-up actions will be required. Accordingly, under the *Radiation Protection Regulations*, a monitoring result that approaches, equals or exceeds an action level could be the first indication that specific follow-up responses are or may be required.

When an action level in a uranium mine or mill code of practice is reached, the licensee should first investigate to determine the cause. This investigation should be implemented as soon as the licensee becomes aware that an action level has been reached. Further, if the investigation confirms that a loss of control of any part of the associated radiation protection program has occurred, the licensee must identify and take corrective actions to restore the effectiveness of the program. If the licensee cannot restore this effectiveness forthwith, the licensee should propose appropriate interim measures for CNSC consideration.

In addition to conducting an investigation when any action level in a CNSC licence is reached, the licensee is obliged by law to identify and take corrective action to restore the effectiveness of the associated radiation protection program.

When proposing measures to restore the effectiveness of radiation protection programs after any action level in a licence is reached, applicants for CNSC licences may propose for CNSC consideration the measures that they consider appropriate to their respective circumstances. These proposals should be based on credible experience, data or analyses, and should take into account the consequences of any loss of control. Typically, the greater the actual or potential radiation hazards if an action level is reached, the more immediate, complex or rigorous the proposed response measures should be.

In addition to identifying and undertaking corrective actions if an action level in a licence is reached, the licensee must notify the CNSC within the period specified in the licence.

6. Examples of the Use of Action Levels

In the past, the practical application of performance indicators has provided AECB licensees with advance warning of the imminent loss of control or deterioration of their radiation protection programs. Some examples of such uses follow.

6.1 Uranium mines and mills

Uranium mining and milling operations have proposed and used action levels within the framework of "codes of practice" to help assure the radiation safety of workers, on-site personnel and the public. Traditionally, these action levels have been based on both facility-specific and industry experience.

The proposed *Uranium Mines and Mills Regulations* stipulate that applications for licences shall include a "code of practice" that contains any action level that the applicant considers appropriate, as well as the proposed responses and reporting procedures if a proposed action level is reached.

The AECB draft Regulatory Guide, C-218, *Preparing Codes of Practice to Control Radiation Doses at Uranium Mines and Mills*, provides guidance on developing and submitting codes of practice for uranium mines and mills.

At a given mine or mill, separate codes of practice may be needed for different operations. Any action level and related responses contained in a proposed code of practice should be tailored to the specific situation and its needs. Possible responses could range from a requirement for increased monitoring to the suspension of related operations.

6.2 Nuclear power plants

Under the *NSC Act* and proposed regulations, applicants for nuclear power plants licences will be able to propose facility-specific action levels that are not expressly linked to a percentage of the radiation dose limit for members of the public. (See AECB draft Regulatory Policy, C-118 (Rev.1), *Operating Release Levels for Nuclear Facilities*.)

6.3 Medical and research institutions

Medical and research institutions commonly use open sources of radiation. Accordingly, radiation protection programs at such institutions frequently require precautionary monitoring to screen for significant radionuclide intake by employees.

Some medical and research institutions that use radioiodine have historically established criteria for taking remedial actions in response to the results of thyroid monitoring programs. Typically, when the measured thyroid burden reached or exceeded defined levels, specific responses were called for, and implemented. These responses consisted of such actions as repeating the thyroid counting procedure to verify a result, performing bioassays on co-workers, or implementing measures to prevent further exposure of the workers until the cause was identified and remedied.

6.4 Radioisotope use

In licences authorizing radioisotope use, the AECB routinely included conditions that obliged the licensee to carry out certain actions if specified surface contamination criteria were reached or exceeded. If contamination monitoring indicated that a surface was contaminated to a level that reached or exceeded a predetermined criterion, the licensee was typically required to clean the affected work surfaces to lower radioactive contamination to an acceptable level.

The above approach was an essential part of the licensee's radiation protection program, and the associated contamination criteria served a purpose similar to that of action levels. Accordingly, under the *NSC Act* and regulations, some applicants for licences authorizing radioisotope use may choose to propose the use of action levels that are expressed in terms of surface contamination levels.